

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 12 MAY 2005

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Applicant's or agent's file reference 028750-236	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/US04/08399	International filing date (day/month/year) 19 March 2004 (19.03.2004)	Priority date (day/month/year) 19 March 2003 (19.03.2003)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 9/16 and US Cl.: 424/490		
Applicant UNIVERSITY OF KENTUCKY RESEARCH FOUNDATION		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of ___ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>		
Date of submission of the demand 19 January 2005 (19.01.2005)	Date of completion of this report 29 April 2005 (29.04.2005)	
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer BLESSING FUBARA Telephone No. 571-272-1600	

Form PCT/IPEA/409 (cover sheet)(January 2004)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US04/08399

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4)
- ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):

☒ the international application as originally filed/furnished

☐ the description:

pages 1-41 as originally filed/furnished

pages* NONE received by this Authority on _____

pages* NONE received by this Authority on _____

☒ the claims:

pages 42-45 as originally filed/furnished

pages* NONE as amended (together with any statement) under Article 19

pages* NONE received by this Authority on _____

pages* NONE received by this Authority on _____

☒ the drawings:

pages 1-8 as originally filed/furnished

pages* NONE received by this Authority on _____

pages* NONE received by this Authority on _____

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (specify): _____
- ☐ any table(s) related to the sequence listing (specify): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (specify): _____
- ☐ any table(s) related to the sequence listing (specify): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/08399**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)

Claims 1-15

YES

Claims NONE

NO

Inventive Step (IS)

Claims 1-15

YES

Claims NONE

NO

Industrial Applicability (IA)

Claims 1-15

YES

Claims NONE

NO

2. Citations and Explanations (Rule 70.7)

Claims 1-15 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a microsphere composition comprises a composite of PLGA, polyacryloyl hydroxyethyl starch and a biologically active compound.

Claims 1-15 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability in the polymer drug delivery art and the subject matter claimed can be made or used in industry.

Deluca et al. (US 5,160,745) discloses biodegradable three dimensional microspheres and biologically active macromolecular agents are entrapped within the polymer network (abstract). Preferred biologically active macromolecular agents are peptides and proteins (column 3, lines 53-68; column 7, lines 3-16). The biodegradable 3-d polymers are hydrophilic and can include derivatives of polysaccharides such as hydrolyzed amylopectin; an example of which is hydroxyethyl starch (HES) (column 5, lines 6-10). The 3-d hydrophilic net work is obtained by free radical polymerization of two vinyl or substituted vinyl groups such as acryloyl (column 5, lines 38-63) with additional monovinyl monomer such as N-acryloyl-N'-dimethylamino propylamine (column 6, lines 57-68). Similarly, acryloyl chloride can react with hydroxyl or amino groups of the biodegradable hydrophilic polymer (column 6, lines 2-7). The system of Deluca does not have PLGA to form a composite with the hydroxyethyl starch (HES).

Berde et al. (US 5,922,340) discloses a sustained release microsphere composition that comprises controlled release biocompatible carriers selected from the group consisting of PLGA, polyorthoesters, polycaprolactones, soluble derivatives of polysaccharides such as HES (column 8, lines 37-65) and biologically active agent (claim 7).

There is no teaching in the references to form composite of the PLGA and the hydroxyethyl starch (HES) that has been derivatized with acryloyl chloride.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US04/08399

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 7 is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claim is indefinite for the following reason(s): Claim 7 depends from claim 4 and claim 4 or the claim from which it depends from does not recite a primate and claim 7 does not have antecedence for primate.